UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

MISSOURI, KANSAS, and IDAHO,
Intervenor-Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants,

and

DANCO LABORATORIES, LLC,
Intervenor-Defendant,

and

GENBIOPRO, INC.,
Intervenor-Defendant.

Case No. 2:22-cv-00223-Z

DANCO'S REPLY IN SUPPORT OF MOTION TO DISMISS INTERVENOR-PLAINTIFFS' AMENDED COMPLAINT

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INTRODUCTION

The States cannot cure the fundamental defects in their suit. Missouri, Kansas, and Idaho lack venue in *Texas*. As intervenors, the States cannot piggyback on the Alliance Plaintiffs' dismissed, jurisdictionally defective lawsuit. The States also lack standing in their own right; their counterarguments rewrite fundamental Article III standing rules. To top it off, the States failed to administratively exhaust their claims and their challenge to the 2016 changes is untimely. The States' amended complaint should be dismissed.

ARGUMENT

I. Missouri, Kansas, And Idaho Plainly Lack Venue In Texas.

The States do not dispute that no party resides in this district. 28 U.S.C. § 1391(e)(1)(A), (C). They do not defend the basis for venue asserted in their Complaint—that "a substantial part" of the events "giving rise to the claims occurred in this district." ECF No. 217 ¶ 34. Nor do the States contest that "[a]n existing suit within the court's jurisdiction is a prerequisite" to intervention. *Harris v. Amoco Prod. Co.*, 768 F.2d 669, 675 (5th Cir. 1985) (citation omitted). Those concessions end this case: There is no independent basis for venue, and there is no "existing suit within the court's jurisdiction" because the Alliance Plaintiffs "lack standing to challenge FDA's actions," *FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 374 (2024), meaning "the District Court did not have jurisdiction," *United States v. Texas*, 599 U.S. 670, 686 (2023).

The States' insistence that they may nevertheless proceed in this district hinges on the remarkable assertion that the Alliance Plaintiffs "did have standing when they sued." ECF No. 228 at 2. Accepting that argument requires outright defying the Supreme Court's 9-0 decision that the Alliance Plaintiffs "lack standing to challenge FDA's actions." *Alliance*, 602 U.S. at 374; *see Alliance for Hippocratic Med. v. FDA*, 117 F.4th 336, 340, 342 (5th Cir. 2024) (Ho, J., concurring) (lower courts must "follow [Supreme Court] precedents, whether [they] agree with them or not").

The States do not identify any case in which a court allowed a plaintiff to piggyback on a lawsuit over which the court lacked jurisdiction. Nor can the States distinguish the authorities holding courts must dismiss or transfer a case once the venue-creating party is dismissed. *E.g.*, ECF No. 222 at 9-10 n.1. The States assert (without citation) that these cases involve situations where the venue-creating plaintiff "is conclusively determined to lack standing at the outset." ECF No. 228 at 9. But Danco cited multiple cases decided at summary judgment or years into litigation.[1] The States also insist that these cases hold "only that a court can transfer or dismiss a case where it determines that the party satisfying venue lacks standing." *Id.* But there is no such discretion: When "venue is improper," "the case must be dismissed or transferred under § 1406(a)." *Atl. Marine Constr. Co. v. U.S. Dist. Ct. for W. Dist. of Tex.*, 571 U.S. 49, 56 (2013).

The States' other arguments are wrong and irrelevant. The Supreme Court did not hold the Alliance Plaintiffs "lost standing," ECF No. 228 at 2; it unanimously concluded the Alliance Plaintiffs "lack standing." *Alliance*, 602 U.S. at 374. Mootness, not standing, "addresses whether an intervening circumstance has deprived the plaintiff of a personal stake in the outcome of the lawsuit," *West Virginia v. EPA*, 597 U.S. 697, 719 (2022) (citation, quotation marks, and brackets omitted), and the Supreme Court did not hold the Alliance Plaintiffs' suit moot.[2] That means the

[1] *E.g.*, *Kruse v. Wells Fargo Home Mortg., Inc.*, No. 1:02-cv-03089, 2006 WL 1212512, at *1 (E.D.N.Y. May 3, 2006); *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-00156, 2024 WL 3741510, at *3 (S.D. Ohio Aug. 8, 2024); *Ga. Republican Party v. SEC*, 888 F.3d 1198, 1201 (11th Cir. 2018); *Merchs. Fast Motor Lines, Inc. v. ICC*, 5 F.3d 911, 914, 921-922 (5th Cir. 1993).

[2] The States ascribe their "lost standing" theory to Judge Ho, ECF No. 228 at 2, 8, but his concurrence said only that this Court and the Fifth Circuit believed Plaintiffs had standing, but the Supreme Court held otherwise. 117 F.4th at 340, 342 (Ho, J., concurring). Judge Ho *never* suggested the Alliance Plaintiffs had standing before the Supreme Court's decision. After all, standing is assessed "at the time the action commences," *Stringer v. Whitley*, 942 F.3d 715, 719, 724 (5th Cir. 2019) (citation omitted), and "if the [plaintiff] lacks standing, then there is no Article III suit to begin with," *Flecha v. Medicredit, Inc.*, 946 F.3d 762, 769 (5th Cir. 2020). Moreover, the Government did not change its position, *contra* ECF No. 228 at 2; *see Alliance for Hippocratic*

Alliance Plaintiffs *never* had the interest necessary to invoke this Court's jurisdiction.

The States cannot avoid dismissal by recasting the motions to dismiss as motions to reconsider this Court's intervention ruling. Even if Danco and the Government had moved for reconsideration, the "clearly erroneous" standard would not apply. *Contra* ECF No. 228 at 9. Reconsideration prior to judgment is governed by Rule 54(b), which permits the court "to reconsider and reverse its decision for any reason it deems sufficient." *Austin v. Kroger Tex., L.P.*, 864 F.3d 326, 336 (5th Cir. 2017) (per curiam) (citation omitted). It would be "sufficient" for this Court to correct its abuse of discretion in granting intervention "based on an erroneous view of" standing law. *Id.* at 329 (citation omitted).

Finally, the States argue (at 6) that Danco waived its venue challenge by intervening. But Danco intervened in the Alliance Plaintiffs' lawsuit *before* the States intervened. Since then, Danco and the Government have objected to the States' venue at every step. *See* ECF No. 212 at 5. Danco's intervention two years before the States filed their amended complaint does not "deprive [Danco] of any of [its] procedural defenses." *SEC v. Ross*, 504 F.3d 1130, 1150 (9th Cir. 2007). In any event, the Government's venue objection puts the issue squarely before the Court.

II. This Court Lacks Jurisdiction Over The States' Claims.

A. The States Cannot Piggyback On A Dismissed, Jurisdictionally Defunct Suit.

The States brush aside Danco's and the Government's jurisdictional objections, claiming that the Fifth Circuit allows "intervention as of right in a jurisdictionally and procedurally proper suit that has been dismissed voluntarily." ECF No. 228 at 10 (quoting *Sommers v. Bank of Am.,*

Med. v. FDA, 78 F.4th 210, 236 (5th Cir. 2023) ("[FDA and Danco] defend FDA's actions on the ground that federal law would allow the Doctors to refuse care based on a conscientious objection."), and any (nonexistent) change was irrelevant to the Supreme Court's holding that the Alliance Plaintiffs lack standing "[n]ot only as a matter of law" because federal conscience laws "speak clearly," "but also as a matter of fact" because the Alliance Plaintiffs had not alleged "any instances" where doctors were forced over objections to provide care. 602 U.S. at 387-388.

N.A., 835 F.3d 509, 513 n.5 (5th Cir. 2016)). The States also make much of *Harris*, *see id.* at 7-10, which allowed the intervenor to "continue litigating after the main plaintiffs ha[d] settled out of a lawsuit" over which the court had jurisdiction. 768 F.2d at 682. Therein lies the crucial distinction: These cases involve an original "jurisdictionally and procedurally proper suit," which never existed here because the Alliance Plaintiffs (1) lacked standing, and (2) their voluntary dismissal without prejudice "leaves the situation as if the action had never been filed," and takes down with it interlocutory orders like intervention. ECF No. 222 at 11-12 (quoting *Long v. Bd. of Pardons & Paroles of Tex.*, 725 F.2d 306, 307 (5th Cir. 1984)).

B. The States Lack Standing.

1. The States allege indirect economic injuries connected to FDA's actions by a long, convoluted chain of independent actors—the same kind of expansive theory based on the "indirect effects" of "federal policies . . . on state revenues or state spending" the Supreme Court has rejected as too "attenuated" under Article III. *Texas*, 599 U.S. at 680 n.3. The States do not mention *Texas* at all in discussing economic injury, and they have no counter to the fact that their capacious theory would sweep in challenges by States to almost every federal action. *See* ECF No. 222 at 16-17.

The States instead trot out an inapplicable truism. Monetary harm can confer standing—but not the States' attenuated, speculative allegations of future Medicaid or insurance costs. The States' cited cases (at 16-17) fall far short of helping them here. *TransUnion LLC v. Ramirez*, 594 U.S. 413, 425 (2021), merely recites the rule that monetary harm can be concrete injury. And the challenged program in *Biden v. Nebraska* "directly injure[d]" the State by costing it "$44 million a year in fees" under existing contracts. 600 U.S. 477, 489-490 (2023). FDA's challenged actions do not directly impact the States' finances, *see* ECF No. 222 at 15-16—hence why they can only speculate about "distant . . . ripple effects" on their budgets. *Alliance*, 602 U.S. at 383.

The States (at 19) also quote *Alliance*'s recital that "government regulation of a third-party

individual or business may" "cause injury in fact to an unregulated plaintiff." 602 U.S. at 384. But not *all* unregulated plaintiffs conceivably touched by government action experience Article III injury. Nor are the States analogous to the car insurance plaintiffs that directly bore the costs of relaxed motor vehicle safety standards in *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983). Indeed, the States' theory would permit them to take those car insurers' places and challenge federal car safety regulations simply because Medicaid covers some of the "hundreds of thousands" injured in traffic accidents. *Id.* at 33. In any event, *State Farm* "assumed [standing] without discussion," and such "drive-by jurisdictional rulings . . . have no precedential effect." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 91 (1998).

The States try (at 18) to close the glaring gaps in their standing theory by citing *Department of Commerce v. New York*, 588 U.S. 752 (2019). In that case, States alleged that adding a census citizenship question would cause noncitizen residents to fail to respond, leading to a direct loss of federal funds distributed based on state population. *Id.* at 767. The Supreme Court found standing because adding the question would reduce response rates among noncitizens, "rendering the causal link between the addition of the question and the loss of federal funds sufficiently direct." *Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022) (Sutton, J.). By contrast, FDA's actions do "not impose any direct costs on the States or threaten the loss of any federal funding"; "[a]ny downstream costs . . . to the States come about via" discretionary choices of independent actors and "the States' other social-welfare policy choices." *Id.*; *see also Murthy v. Missouri*, 603 U.S. 43, 68 n.8 (2024).

Even setting that aside, the States cannot identify a single instance in which they paid for care traceable to each of FDA's challenged actions, as opposed to the 2000 approval. Instead, they cite vague figures like an "estimate" that "a dozen" Missouri Medicaid enrollees experience "abortion-drug ER visits" each year, ECF No. 228 at 17; ECF No. 217 ¶ 694, claiming this proves

that *somewhere* in their annual budget (Medicaid or public hospital line item), they ultimately pay for *something* (physical or mental healthcare) for *someone* (Medicaid enrollee or public employee) because of a medication abortion traceable to the challenged actions.[3] That is about as far from "direct costs" as one can get. *See Arizona*, 40 F.4th at 386. It plainly is not a "much closer" connection than in *Department of Commerce*. *Contra* ECF No. 228 at 19. The States' response—pointing (at 18-20) to the generic approval and an alleged increase in *all* abortions, including medication abortions, "from all of FDA's actions"—just highlights these problems. It does nothing to trace alleged costs to each challenged change, as required to allege "standing for each claim that they press." *TransUnion*, 594 U.S. at 431.

The States' suggestion (at 20) that Danco needs standing further displays their confusion. Danco is not invoking this Court's jurisdiction; it is the *States*' "right to be here," ECF No. 228 at 20, that depends on establishing standing—which requires alleging injuries causally linked to each of FDA's challenged actions. For the reasons explained, they have not.

2. The States also lack standing based on their milieu of "sovereign harms." ECF No. 228 at 11. *First*, the States do not have standing based on the so-called "risk of federal preemption and federal interference with enforcement of state law." *Id.* at 12. Their "evidence" of imminent harm is former Attorney General Garland's comment that "States may not ban Mifepristone based on disagreement with the FDA's expert judgment about its safety and efficacy." ECF No. 217 ¶¶ 250-251. That focus on the underlying 2000 approval shows the States cannot trace their injuries to the post-2000 actions they challenge. *See Lewis v. Casey*, 518 U.S. 343, 357 (1996). Years after

[3] Danco cited the States' own complication data to highlight that the chain of calculations behind their economic harms estimate—which is already "too speculative or otherwise too attenuated to establish standing," *Alliance*, 602 U.S. at 390—*also* is replete with statistical cherry-picking. *See* ECF No. 222 at 16-17 n.5. Regardless, the Court can take judicial notice of these relevant, publicly available facts. *See, e.g.*, *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011).

the FDA actions that Missouri, Kansas, and Idaho *do* challenge took effect, none of those States have been sued—by the federal government or anyone else. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (risk of injury must be "certainly impending" (citation omitted)).

United States v. Texas also bars the States' suit. As in that case, the States here cannot maintain a lawsuit against the federal government based on its deregulatory actions or alleged underenforcing of federal law. 599 U.S. at 681. Nor can FDA's actions, which in no way limit States' abilities to pass their own laws restricting mifepristone, "make legal under state law what used to be illegal." ECF No. 228 at 14. The States again invoke *Department of Commerce* (at 14-15), but that case said nothing about supposed downstream effects of federal law on state law. For good reason: Allowing standing on that basis would be "unprecedented and limitless," *Alliance*, 602 U.S. at 391, as it is "not at all uncommon for the Federal Government to permit activities that a State chooses to forbid or heavily restrict," *Gamble v. United States*, 587 U.S. 678, 690 (2019).

Second, the States' vague assertions of "sovereign 'benefits' " that "flow from participation in the federal system" cannot confer standing. ECF No. 228 at 15 (quoting *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 608 (1982)). "A State does not have standing as *parens patriae* to bring an action against the Federal Government." *Snapp*, 458 U.S. at 610 n.16. As *Snapp* explained, when a State sues to "secur[e] observance of the terms under which it participates in the federal system," that is a suit arising "[i]n the context of *parens patriae* actions" because it seeks to enforce "the benefits that are to flow from participation in the federal system." *Id.* at 607-608. That is exactly what the States are attempting here.[4] Moreover, the States' attempt

[4] The States' citation (at 15) to *Crow Indian Tribe v. United States*, 965 F.3d 662 (9th Cir. 2020), is equally misplaced. That case found standing to challenge the vacatur of a rule delisting grizzly bears as endangered species; the plaintiff States could only regulate grizzly hunting if the delisting rule was in place. *See id.* at 676. FDA's regulations impose a floor—not a ceiling.

(at 15) to characterize the supposed "risks of mifepristone as harms to the state itself is a 'thinly veiled attempt to circumvent the limits on *parens patriae* standing.'" *Washington v. FDA*, 108 F.4th 1163, 1178 (9th Cir. 2024) (quoting *Murthy*, 603 U.S. at 76).

Finally, the States' population-loss theory is not supported by *Department of Commerce* either. The injury in that case was not "mere undercounting," as the States claim (at 16). Undercounting in connection with the census led directly to cognizable injuries like "the concomitant loss of congressional seats and federal funding." *Murthy*, 603 U.S. at 68 n.8. If undercounting or population loss could alone establish standing, any State could challenge any federal action that could impact the State's population count, even years in the future.

III. The States Failed To Exhaust Administrative Remedies, And No Exception Applies.

FDA's regulations and a litany of cases show parties must exhaust administrative remedies prior to suing. ECF No. 219 at 12-13; ECF No. 222 at 21-22. The States' only response is that FDA's regulations do not include the term "inoperative." ECF No. 228 at 23 (quoting 5 U.S.C. § 704). That provision applies only when dealing with "an appeal to superior agency authority," 5 U.S.C. § 704, which FDA's exhaustion requirement is not, *see* 21 C.F.R. § 10.30(e); *cf. Darby v. Cisneros*, 509 U.S. 137 (1993) (petitioner failed to appeal hearing officer decision to Secretary).

The Court should not excuse the States' failure to exhaust. Unlike in *Harris*, 768 F.2d at 678-682, where the issues fully overlapped, the Alliance Plaintiffs' citizen petition omitted several of the States' challenges—including those pertaining to State law. The Alliance Plaintiffs also never filed citizen petitions challenging FDA's 2021 or 2023 actions. Courts regularly hold that FDA deserves a "fair and full opportunity" to evaluate claims like the States' in the first instance. *Woodford v. Ngo*, 548 U.S. 81, 90 (2006). For these same reasons, the States have made no showing that exhaustion would be futile. *Tesoro Refin. & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009). And if FDA delays responding to a citizen petition by the States, the States can

sue over *that*. 5 U.S.C. § 555(b).

The States also argue (at 23-24) that exhaustion is not required if the agency exceeds its authority. But the case from which they derive that theory *declined* to excuse a failure to exhaust and said in *dicta* that an exception might be warranted if agency action was "in excess of statutory authority," "likely to result in individual injustice," "disruptive of the legislative scheme," and "contrary to an important public policy." *Myron v. Martin*, 670 F.2d 49, 52 (5th Cir. 1982). None of the States' challenges tick all those boxes—especially not the challenge to the 2016 changes, the thrust of which is an arbitrary-and-capricious argument about "interrelated" changes. ECF No. 217 ¶ 760.

IV. The States' Challenge To The 2016 Changes Is Time Barred.

The States' challenge to the 2016 changes is untimely. *First*, "Intervenors' claims cannot relate back to the original filing date" when the court lacked "subject-matter jurisdiction over the original complaint." *Lopez v. Sw. Airlines Co.*, No. 3:08-cv-01975, 2013 WL 12121233, at *6 (N.D. Tex. July 10, 2013); *e.g.*, *White v. Louisiana*, 178 F.3d 1291 (5th Cir. 1999) (per curiam). When a party "intervene[s] after the statute of limitations" has "expired" and the original plaintiffs lacked standing, there is nothing for the intervenor's claims to "relate back to." *Lopez*, 2013 WL 12121233, at *2. As for *Harris*, the statute there required parties to file a charge with the agency before suing; if the agency sued on its own behalf, it had to first investigate the claims. 768 F.2d at 672, 676 & nn.2, 4. Private parties sued, the agency intervened, the private parties settled. The agency could proceed because exhaustion was satisfied; *Harris* said nothing about timeliness.

Second, the States' "right to file suit" arose in 2016, when the challenged changes occurred. *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 809 (2024) (quotation marks omitted). Even before *Dobbs*, Idaho and Missouri limited prescribing rights to physicians, Idaho required "reasonable efforts" to ensure in-person follow-ups, and Missouri required two in-

person appointments. Idaho Code §§ 18-607(2), 18-617, 18-608A; Mo. Rev. Stat. §§ 188.021, 188.020, 188.080. Post-*Dobbs*, Idaho still permits abortions at ten weeks and beyond in certain circumstances, and Missouri still permits abortions up to viability. Idaho Code §§ 18-622, 18-608; *see* ECF No. 222 at 19; *CHPPGP v. State*, No. 2416-CV31931 (Mo. Cir. Ct., Jackson Cnty. Dec. 20, 2024) (enjoining 8-, 14-, 18-, and 20-week bans), *as amended* (Feb. 14, 2025). And Kansas, whose Constitution guarantees abortion rights, cannot identify any post-*Dobbs* changes.

Third, for these reasons, even assuming binding precedent is a "legal disability" for tolling purposes—which the States provide no support for—*Roe* did not impose such a disability. *See* 28 U.S.C. § 2401(a) & notes (explaining this term was used to describe minors or mentally impaired).

Fourth, *Corner Post* cannot save the States. Justice Jackson's dissent warned of challenges by a "brand new entity"—which the States are not. 603 U.S. at 861-862 (Jackson, J., dissenting). Nor can the States invoke a continuing injury theory. Their alleged injury from FDA's lack of "legal authority when issuing the" 2016 changes accrued in 2016. ECF No. 217 ¶ 758.

Finally, the 2021 citizen petition denial did not reopen the 2016 changes. The Fifth Circuit never said otherwise; it held that "[t]he record does not bear out" the claim that "FDA reopened the 2000 Approval" in 2021. *Alliance*, 78 F.4th at 244. Nor is it enough that FDA's 2021 denial "reviewed the [2016] conditions for use." *Id.* The 2021 decision did not "significantly alter[ ] the stakes of judicial review." *Nat. Res. Def. Council v. EPA*, 571 F.3d 1245, 1266, 1270 (D.C. Cir. 2009) (per curiam) (citation omitted). If the fact that one agency action is "related" to another could "restart the . . . clock," no agency action would ever be final. *Nat'l Mining Ass'n v. U.S. Dep't of Interior*, 70 F.3d 1345, 1351 (D.C. Cir. 1995).

CONCLUSION

The Court should grant the motions to dismiss the States' amended complaint.

Respectfully submitted,

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May 5, 2025

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with Local Rule 7.2 in that it does not exceed 10 pages.

/s/ Jessica L. Ellsworth
Jessica L. Ellsworth

CERTIFICATE OF SERVICE

I certify that on May 5, 2025, I electronically filed the foregoing using the CM/ECF system. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties of record.

/s/ Jessica L. Ellsworth
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